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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,750	01/23/2004	Ulrich Diermann	14476.01	7620

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EXAMINER

KENNEDY, SHARON E

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,750

Applicant(s)

DIERMANN ET AL.

Examiner

Sharon Kennedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 10/226,104.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/23/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Double Patenting

Claims 1-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,706,009. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application encompass the claims of the parent.

It is becoming common to delay filing the terminal disclaimer(s) until all the claims are indicated as allowable. However, this places a burden on the examiner and the USPTO to conduct additional paper processing, docketing, and examination. Accordingly, applicant must file the terminal disclaimer(s) in response to this office action or supply substantive arguments against the double patenting rejection(s).

Claim Rejections - 35 USC § 112

Claims 1-12, 25-33, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 states "wherein the injection needle protrudes through and seals the intake opening of the perfusion catheter when the injection needle is in the forward portion...". This has not been

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previously disclosed and even contradicts what is intended in the original disclosure. Figure 3a and the distal end of the perfusion device are noted. However, see sheet 3 of the drawings wherein the needle and the catheter have different cross sections which permit perfusion when the needle is in all positions. See also column 8, lines 13+ of the parent patent. The cross-sectional shapes are adapted such that a sufficient flow always remains over the entire flow length of the perfusion catheter even if it tightly wrapping around the needle. Accordingly, the examiner takes the position that the embodiments now claimed and not only not originally disclosed, but even contrary to the original invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, applicant states in the preamble that the device is "connectable" to a perfusate supply, however, in line 6, the injection needle is "in fluid communication" with the perfusate supply. Accordingly, it is unclear if the perfusate supply is claimed or not. To correct, applicant should insert --adapted to be—after "end" in line 6 of claim 1.

Claim Rejections - 35 USC § 102

Claims 1, 2, 9, 13, 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipate by McIntyre, US 4,014,333. See especially figure 2, perfusion holes 15 and 16. Note the end appears to be sealed (figure 5). The claimed casing could be interpreted to be segment 19. Regarding claim 9, the supply catheter is interpreted to be the syringe 11

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Claims 13 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by McLaughlin, US 4,096,860. This reference was applied in the parent application and reference is made to the prosecution history therein. Claim 13 recites that the discharge opening of the injection needle resides within the perfusion catheter when the injection needle is in the retracted position. This functional language is contrary to the intended use of the McLaughlin; however, the claim is an article claim and does not recite any features which structurally distinguish over McLaughlin. It is contrary to the MPEP to allow claims of this nature. See MPEP 2114, section entitled, "Apparatus Claims Must Be Structurally Distinguishable From The Prior Art." An apparatus claim must cover what a device is, not what it does.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.



Sharon Kennedy
Primary Examiner
Art Unit 3762

Sek